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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,968	02/13/2002	Heinrich Wieland	38891.00100	6225

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MILBANK, TWEED, HADLEY & MCCLOY LLP
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WASHINGTON, DC 20006

EXAMINER

HANLEY, SUSAN MARIE

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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07/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/049,968

Applicant(s)

WIELAND ET AL.

Examiner

SUSAN HANLEY

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2009.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-71 is/are pending in the application.
4a) Of the above claim(s) 70 and 71 is/are withdrawn from consideration.
5) ☒ Claim(s) 69 is/are allowed.
6) ☒ Claim(s) 54, 55, 58, 59, 61-63 and 66-68 is/are rejected.
7) ☒ Claim(s) 55-57, 60, 64 and 65 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 13 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-849)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of specie I (claims 54-69) in the reply filed on 04/03/2009 is acknowledged.

Claims 70 and 71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/3/09.

The EPO machine translation (description and claims) of WO 97/36570 (Schmidt et al.) is provided to complete the record since said WO document is in German.

Withdrawal of Rejections

The rejections not explicitly restated below are withdrawn due to Applicant's response in the amendment filed 11/13/2008.

New Grounds of Rejection and Objection

Specification

The specification is objected to because it lacks a brief description of the drawings.

Claim Objections

Claim 55 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The pharmaceutical

composition is administered topically in the claim from which claim 55 depends, claim 54.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 54, 55, 58, 59, 61-63, 66, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Bonte (WO 99/62481; English language equivalent is US 6,471,972).

Bonte discloses a method of identifying subjects having wrinkles around the eyes, applying a cream (topical, as in instant claims 54, 55 and 68) twice a day and evaluating the effect on the wrinkles of the subject. The cream comprises magnesium aspartate and excipients. The results show that the cream had a significant positive effects for decreasing the total surface area, the number of wrinkles and total length of the wrinkles (col. 5, line 37 through col. 7, line 61 and pages 8-12 of the WO document). Bonte teaches that magnesium salts promote the adhesion of the keratinocytes to the epidermal basal layer to the dermo-epidermal junction, especially to the collagen IV of said junction. Bonte teaches that particularly remarkable results are obtained when the adhesion promoter is applied in association with a stimulant of collagen IV or VII synthesis (col. 1, lines 29-67; page 1, line 10 through page 2, line 14 of the WO document). In a preferred embodiment, the stimulant of collagen IV synthesis

is a soya saponins or a soya sapogenol from plant extracts such as soya (glycine Max; e.g., soya glycines) (instant claims 58, 59, 61-63 and 67; col. 2, lines 13-28; page 2, lines 24-28 of the WO document). Bonte teaches an anti-wrinkling tightening gel comprising soya saponin (Example 5 of '972 and Example 5, page 13 of the WO document; claims 61-63).

Bonte does not disclose a method of identifying a subject having wrinkles and administering an effective amount of a composition comprising a magnesium salt and plant extracts comprising soya saponins and soya sapogenols from soya (Glycine max).

It would have been obvious to one of ordinary skill in the art, a dermatologist, at the time the invention was made to identify a subject having wrinkles and to administer an effective amount of a composition comprising a magnesium salt and an extract from soya (Glycine max). The ordinary artisan would have been motivated to do so because Bonte teaches that particularly remarkable results are obtained when an adhesion promoter such as a magnesium salt is administered with a stimulant of collagen IV synthesis, an extract of soya glycines. The ordinary artisan would have had a reasonable expectation that the combination of a magnesium salt and an extract of soya (Glycine max) would be effective to treat wrinkles because Bonte teaches that the combination is effective.

The instant claim language uses the transitional phrase "comprising". The term "comprising" is open language. Hence, the prior art cream for treating wrinkles can contain additional elements (e.g., magnesium salts) that are encompassed by, but not specifically named, by the claims.

Bonte does not teach that an extract containing soya glycinines is an aromatase inhibitor. However, these claimed effects do not make the instant claims patentable over the prior art because the effect of an extract of soya glycinines on aromatase is reasonably interpreted as an inherent property of the compound.

MPEP 2112.02: PROCESS CLAIMS - PRIOR ART DEVICE ANTICIPATES A CLAIMED PROCESS IF THE DEVICE CARRIES OUT THE PROCESS DURING

Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. *In re King*, 801 F.2d 1324, 231USPQ 136 (Fed. Cir. 1986) See also *In re Best*, 562F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993)

Further, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Claims 56, 57, 60, 64 and 65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 69 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

/Susan Hanley/
Examiner, Art Unit 1651

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